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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	F. Andrew UBEL et al.	Group Art Unit:	3728
Serial No.:	09/551,706	Examiner:	T. Arnold
Filed:	18 April 2000	Docket No.:	55019 US 002
		Confirmation No.:	2678

Title: APPARATUS AND METHODS FOR PACKAGING AND STORING MOISTURE-SENSITIVE PRODUCTS IN RESEALABLE POUCHES

Assistant Commissioner for Patents
Washington, D.C. 20231

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Fee Calculation for Claims Pending After Amendment					
	Pending Claims after Amendment (1)	Claims Paid for Earlier (2)	Number of Additional Claims (1-2)	Cost per Additional Claim	Additional Fees Required
Total Claims				x $18 =	
Independent Claims				x $84 =	
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#16 Brief 6 Letter 5/17/02

PATENT
Docket No. 55019 US 002 *(Formerly 55019USA1A)*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	F. Andrew UBEL et al.	)	Group Art Unit:	3728
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For: APPARATUS AND METHODS FOR PACKAGING AND STORING MOISTURE-SENSITIVE PRODUCTS IN RESEALABLE POUCHES

APPEAL BRIEF

Assistant Commissioner for Patents
Washington D.C. 20231

Dear Sir:

Applicants present this Appeal Brief in support of the appeal from the final rejections of claims 1-2, 4-23, 25-32, 38-46, and 61-62 of the above-identified patent application as indicated in the Notice of Appeal filed 5 March 2002.

Real Party in Interest

The real party in interest is 3M Innovative Properties Company, as evidenced by the assignment recorded at Reel 011131/Frame 0506.

Related Appeals and Interferences

There are no known related appeals or interferences pending in connection with the present application.

Status of Claims

Claims 1-2, 4-23, 25-32, 38-46, and 61-62 are pending, with claims 3, 24, 33-37, and 47-60 have been withdrawn from consideration. Claims 47-60 were withdrawn as being drawn to a non-elected invention, and claims 3, 24, and 33-37 were withdrawn as being drawn to non-

elected species. Therefore, the final rejection of claims 1-2, 4-23, 25-32, 38-46, and 61-62 is appealed.

Status of Amendments

The remarks proposed in the Response Under 37 C.F.R. § 1.116 dated 18 January 2002 were considered but deemed not to place the application in condition for allowance (*see* Advisory Action dated 4 February 2002). All of pending claims 1-2, 4-23, 25-32, 38-46, and 61-62 are presented in attached Appendix A.

Summary of the Invention

The present invention provides an apparatus that may be used for packaging and storing moisture-sensitive products in resealable pouches. Exemplary embodiments of the apparatus are described in claims 1 and 25, diagrammatically illustrated in Figures 1-7, and generally described at page 7, line 8 through page 16, line 18.

The present invention also provides a closure apparatus for use with products stored within a flexible pouch. Exemplary embodiments of the closure apparatus are described in claim 42, diagrammatically illustrated in Figures 8-11, and generally described at page 16, line 19 through page 18, line 29.

For example, with regard to the apparatus for packaging and storing moisture-sensitive products in resealable pouches, claim 1 describes an apparatus that includes a pouch 200 and a moisture-sensitive product 300. The pouch 200 includes a first end 206, a second end 207, and a pouch length 205 extending between the first end 206 and the second end 207. The pouch defines an interior 202. The pouch 200 may also include an opening 204 proximate the first end 206 that permits access to the interior 202 of the pouch 200.

The moisture-sensitive product 300 has a continuous length and is folded into a packaged configuration including a plurality of sections 302 arranged within the interior 202 of pouch 200 and along the pouch length 205. Each section 302 of the moisture-sensitive product 300 includes at least two folds (e.g., folds 306a and 306b of Figure 3A) and a segment (e.g., generally linear

segment 302b of Figure 3A) spanning between the two folds. The segment (e.g., 302b) also extends along the pouch length 205 as can be seen, e.g., in Figure 2. The moisture-sensitive product 300 may include a moisture-curable orthopedic splinting/casting product.

One folding pattern of product 300 is illustrated in Figures 2 and 3A where product 300 is folded to form a series of repeating S-shaped sections 302 along the length 205 of the pouch 200. As shown in Figure 3A, each section 302 includes a generally linear segment 302b spanning between two folds 306a and 306b. In this particular embodiment, connecting segments 302a and 302c form the remainder of the S-shaped section 302. While described in Figures 2 and 3A as S-shaped sections, other fold configurations are also possible. In general, any packaged configuration that provides discrete sections having one or more segments extending along the length of the pouch is possible, e.g., segments that are parallel to the pouch length or otherwise correspond with the dispensing direction.

While the method used to fold the product 300 can be adapted to take advantage of specific manufacturing equipment or processes, it includes, in one embodiment, first positioning the product 300 to form connecting segment 302a. The product is then folded back on itself along fold 306a to form segment 302b. The product 300 is then folded back on itself again along fold 306b to form connecting segment 302c. Connecting segment 302c then connects to the beginning of connecting segment 302a of the next section (*see* Figure 2) after which the S-shaped sections may repeat.

The apparatus may also include a closure system 400. The closure system 400 may include one or both of a sealing device 500 and a compression device 600. The sealing device 500 seals the opening 204 of pouch 200 before and after dispensing moisture-sensitive product 300. The sealing device 500 is placed over the first end 206 of the pouch 200 and, when in a closed configuration, clamps shut or otherwise substantially hermetically seals the opening 204.

The compression device 600, as described in claim 25 and diagrammatically illustrated in Figures 6-7, is adapted to couple to the pouch 200 proximate the first end 206. The compression device 600 includes a first compression member and a second compression member (e.g., members 602). The second compression member opposes the first compression member. The

compression members 602 are adapted to substantially conform the shape of the first end 206 of the pouch 200 to the shape of the moisture-sensitive product 300, as is illustrated in Figures 6-7. During dispensing, the product 300 moves past the compression device 600 as it is pulled in the direction 306 (*see* Figure 2). In addition to conforming the pouch 200 to the product 300 during dispensing, compression device 600 also tends to smooth the product 300 during dispensing.

With regard to the closure apparatus for use with products stored within a flexible pouch as described in claim 42, the closure apparatus 800 includes a compression device 802 and a sealing device 804 (*see* Figures 8-9). The compression device 802 includes two opposing compression members 806. The sealing device 804 is operatively coupled to the compression device 802 and includes opposing sealing members 810 and 812 that are selectively moveable between an open position and a closed position.

In use, the closure apparatus 800 is placed onto the first end 206 of pouch 200 and positioned so that the product 300 is between the members 806 (*see* Figure 9). The members 806 substantially conform to the shape of the product 300 (*see*, e.g., Figure 7). To dispense product, the sealing member 812 is moved in the direction 818 and the product 300 is pulled in direction 820. When the desired length of product 300 has been dispensed from the pouch and severed from the remaining product, the remaining product can be tucked back into opening 204 a sufficient distance to allow the sealing device 804 to seal the pouch 200.

Issues

I. Whether claim 1 is anticipated under 35 U.S.C. § 102(b) by Nakamura (U.S. Patent No. 5,076,424).

II. Whether claim 1 is anticipated under 35 U.S.C. § 102(b) by Cernohous et al. (WO 96/20884).

III. Whether claims 2, 5-9, 13-15, 17-20, and 22 are anticipated under 35 U.S.C. § 102(b) by Nakamura.

IV. Whether claims 1-2, 4-10, 12-16, 25-28, 32, 38-46, and 61-62 are anticipated under 35 U.S.C. § 102(b) by Parker et al. (U.S. Patent No. 5,003,970).

V. Whether claim 23 is patentable under 35 U.S.C. § 103(a) over Nakamura.

VI. Whether claim 29 is patentable under 35 U.S.C. § 103(a) over Parker et al. in view of Ausnit (U.S. Patent No. 4,703,518).

VII. Whether claims 11, 21, and 30-31 are patentable under 35 U.S.C. § 103(a) over Parker et al.

Grouping of Claims

For the purposes of this appeal, claim 1 stands alone under Issue 1.

For the purposes of this appeal, claim 1 stands alone under Issue 2.

For the purposes of this appeal, claims 2, 5-9, 13-15, 17-20, and 22 do not stand or fall together under Issue III. Instead, claims 2, 5-7, 13-15, 17-20, and 22 stand or fall together, and claims 8-9 stand or fall together.

For the purposes of this appeal, claims 1-2, 4-10, 12-16, 25-28, 32, 38-46, and 61-62 do not stand or fall together under Issue IV. Instead, claims 1-2, 4-7, 13-16, and 61 stand or fall together, claims 8-10, 12, 25-28, 32, 38-41, and 62 stand or fall together, and claims 42-46 stand or fall together.

For the purposes of this appeal, claim 23 stands alone under Issue V.

For the purposes of this appeal, claim 29 stands alone under Issue VI.

For the purposes of this appeal, claims 11, 21, and 30-31 stand or fall together under Issue VII.

Arguments

Claims 1-2, 4-23, 25-32, 38-46, and 61-62 are pending in the present application.

I. Whether Claim 1 is anticipated under 35 U.S.C. § 102(b) by Nakamura

The Examiner rejected claim 1 under 35 U.S.C. § 102(b) as anticipated by Nakamura. The Examiner alleged that Nakamura teaches an apparatus including a pouch 10 with two ends, a length, and an interior, and a moisture-sensitive product 3 having a continuous length. The Examiner further alleged that the product 3 is folded into a configuration that includes a plurality of sections in the interior along the pouch length, where each section includes two folds and a segment spanning therebetween. Further, the Examiner alleged that a "given segment of product 3 as it is shown in Fig[ure] 13 will extend to some degree along the pouch length." Final Office Action at page 2. The Examiner alleged that product 3 of Nakamura "may be defined as 'moisture sensitive' in the broadest sense of the word; the moisture content of the product 3 directly affects its function and visibility." Final Office Action at page 2.

In the Response to Arguments section of the final Office Action at page 7, the Examiner further alleged that the segments taught by Nakamura "have a component which extends upwardly, along the pouch length."

Applicants submit that claim 1 is not anticipated by Nakamura because Nakamura fails to teach each and every element of the claim. For example, claim 1 recites a moisture-sensitive product having a continuous length. A moisture-sensitive product is defined in the Specification as a product that, when exposed to moisture, including ambient humidity levels, rapidly stiffens and forms a cured splint or cast. *See* Specification, page 1, lines 19-21.

In contrast to claim 1, nothing is identified in Nakamura that teaches a moisture-sensitive product as defined by the present invention. Instead, Nakamura teaches "wet tissues, i.e., fibrous materials, such as non-woven fabrics, woven fabrics, or gauze, impregnated with toilet water or cleaning solution ...." Nakamura, column 1, lines 18-20. The wet tissues taught by Nakamura, however, do not anticipate the moisture-sensitive product of the present invention, e.g., they do not rapidly stiffen and form a cured splint or cast.

The final Office Action, however, alleges that "product 3 taught by Nakamura may be defined as 'moisture sensitive' in the broadest sense of the word; the moisture content of the product 3 directly affects its function and usability." This definition of "moisture-sensitive" is not consistent with the definition given by Applicants in the Specification as stated above. Words must be given their plain meaning unless applicant has provided a clear definition in the specification. *See In re Zletz*, 13 U.S.P.Q.2d 1320, 1322 (Fed. Cir. 1989). "Claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their 'broadest reasonable interpretation.'" *In re Marosi*, 710 F.2d 799, 802, 218 U.S.P.Q. 289, 292 (Fed. Cir. 1983) (quoting *In re Okuzawa*, 537 F.2d 545, 548, 190 U.S.P.Q. 464, 466 (C.C.P.A. 1976)) (emphasis in the original). Here, Applicants have provided a clear definition in the Specification for "moisture-sensitive." As Nakamura does not teach a "moisture-sensitive" product consistent with this definition, Nakamura fails to anticipate claim 1.

Further, in the Advisory Action dated 4 February 2002 at page 2, the Examiner alleges "Applicant's 'definition' of moisture-sensitive in lines 19-21 on page 1 of the specification does not prevent the examiner from giving the term its broadest possible interpretation." Yet, as stated above, claims are not to be "read in a vacuum." The Examiner is choosing to ignore the clear definition in the Specification for the term "moisture-sensitive." Further, the Examiner alleged that "exposing Nakamura's product 3 to ambient humidity levels, [sic] would cause it to stiffen, [sic] to some degree." Once again, Nakamura does not teach that product 3 would stiffen when exposed to ambient humidity levels to any degree at all.

Further, claim 1 recites a product having a continuous length, the product being folded into a packaged configuration including a plurality of sections arranged within the interior and along the pouch length. Each section of the folded product includes at least two folds and a segment spanning therebetween, the segment also extending along the pouch length. "Extending along the pouch length" is clearly illustrated (*see* e.g., Figures 2 and 4) and also described in the Specification (*see* e.g., page 10, lines 30-32) as segments that are generally "*parallel* to the pouch length or otherwise correspond with the dispensing direction." For example, as illustrated in Figure 3A, one embodiment of the present invention includes a product 300 that is folded to

form a series of repeating S-shaped sections 302 along the length of the pouch 200. In the illustrated embodiment, a segment 302b spans between two folds 306a and 306b, and extends *along the pouch length.*

The alleged "segment" of Figure 13 of Nakamura does not extend along the pouch length, i.e., there is no identified segment that is parallel to the pouch length, as claimed. Nonetheless, the Examiner alleged that a "component" of the Nakamura segment will extend upwardly along the pouch length "due to the helical arrangement." *See* final Office Action at page 7. Applicants submit that any alleged component that may extend upwardly in the embodiment of Figure 13 of Nakamura does not anticipate a segment extending along (parallel to) the pouch length as recited in claim 1. In fact, the actual "segments" of Nakamura are almost completely transverse to the pouch length rather than parallel thereto. As a result, Nakamura fails to anticipate claim 1.

Even if the clear language of the specification were lacking in this instance, Applicants submit that claim 1 would still be novel in view of Nakamura. That is, to equate the claim language (e.g., *segment extending* along the pouch length) to a mere geometric aspect of the helically wound product of Nakamura would result in a conclusion that *all* three-dimensional objects necessarily *extend* in every conceivable direction. Such a conclusion is inaccurate.

Further, the argument that a "segment" of the product of Nakamura extends along the pouch length ignores the plain language of claim 1. For example, claim 1 recites that each section includes at least two folds and a segment spanning between the two folds. In other words, the segment spans from one fold to another fold. Further, claim 1 recites that the segment also extends along the pouch length. The common meaning of the term "extends" is "to lie or stretch." *See Webster's New World College Dictionary*, 3rd ed., New York (1997). Therefore, according to the plain language of claim 1, the segment lies or stretches along the pouch length. In contrast to this plain language, the Examiner alleges that Nakamura teaches that a component of the product extends along the pouch length. As stated above, the alleged segments of Nakamura lie or stretch (i.e., extend) transverse to the pouch length, not along the pouch length.

For at least the above reasons, Applicants submit that claim 1 is not anticipated by Nakamura.

II. Whether Claim 1 is anticipated under 35 U.S.C. § 102(b) by Cernohous et al.

The Examiner rejected claim 1 under 35 U.S.C. § 102(b) as being anticipated by Cernohous et al. Specifically, the Examiner alleged that Cernohous et al. teaches an apparatus including a pouch 10 with two ends and an interior, and a moisture sensitive product 22 having a continuous length, the product 22 being folded into a configuration including a plurality of sections in the interior along the length. The Examiner further alleged that each section includes two folds and a segment spanning therebetween, the segment also extending along the pouch length.

In the Response to Arguments section of the final Office Action, the Examiner alleged that, while Cernohous et al. teaches that each segment extending between the folds "appears to be horizontal, [each segment] has a component (its thickness) which clearly extends along the pouch thickness."

Applicants submit that Cernohous et al. fails to teach each and every element recited in claim 1. For example, Cernohous et al. does not teach a moisture-sensitive product (e.g., a product that rapidly stiffens and forms a cured splint or cast when exposed to moisture, *See* Specification, page 1, lines 19-21), as recited in claim 1. Instead, Cernohous et al. teaches a sorbent, nonwoven web that contains microfibers so that mass quantities of liquid can be absorbed. *See* Specification at page 5, lines 5-6. This reason alone is sufficient to remove Cernohous et al. as an anticipatory reference.

Further, if the "sections" (e.g., a section, by claim definition, includes two folds and a segment spanning therebetween) of Cernohous et al. are interpreted to be arranged "along the pouch length" (i.e., vertically in Figure 1), then the "segments" of Cernohous et al. necessarily extend *transverse* to the length rather than along the pouch length as claimed. That is, the alleged segments and the sections of Cernohous et al. do not both extend along the pouch length

as claimed and illustrated in the present application (*see*, e.g., Figures 2 and 4). Thus, Cernohous et al. does not anticipate claim 1.

The Office Action asserts, however, that Cernohous et al. teaches that the segments have "a component (its thickness) which clearly extends along the pouch thickness." *See* final Office Action at page 7. Applicants traverse this assertion.

First, claim 1 recites that the segment extends along the pouch length, not along the pouch thickness as asserted by the Office Action. Moreover, as mentioned above, the element "the segment also extending along the pouch length" recited in claim 1 is defined in the Specification as a segment that is generally parallel to the pouch length or otherwise corresponds to the dispensing direction. *See* Specification, page 10, lines 30-32. The Examiner has not identified a corresponding feature of the product in Cernohous et al.

Further, claim 1 recites that the segment extends along the pouch length while also spanning between the at least two folds of each section. As a result, the "thickness" of the material taught by Cernohous et al. cannot be equivalent to the segment recited by claim 1 because the *"thickness"* of the Cernohous et al. product does not span between two folds.

For at least the above reasons, Applicants submit that claim 1 is not anticipated by Cernohous et al.

III. Whether Claims 2, 5-9, 13-15, 17-20, and 22 are anticipated under 35 U.S.C. § 102(b) by Nakamura

The Examiner rejected claims 2, 5-9, 13-15, 17-20, and 22 under 35 U.S.C. § 102(b) as being anticipated by Nakamura. Specifically, the Examiner alleged that Nakamura teaches all of the elements of claims 2, 5-9, 13-15, 17-20, and 22. For example, the Examiner alleged that, in regard to claim 8, item 14 of Nakamura "may" function as a compression device. Regarding claim 13, the Examiner alleged that item 14 "will also function as a sealing device."

Grouped Claims 2, 5-7, 13-15, 17-20, and 22

Claims 2, 5-7, 13-15, 17-20, and 22, each of which depend, either directly or ultimately, from claim 1, are not anticipated by Nakamura for the same reasons as stated above for the anticipation rejection of claim 1 in view of Nakamura. In addition, claims 2, 5-7, 13-15, 17-20, and 22 each recite additional elements that further support patentability when combined with claim 1. For example, Nakamura does not teach a moisture-sensitive product within the clear definition of the term stated in the Specification of the present invention. Further, Nakamura does not teach that the segments of the folded product extend along the pouch length.

For at least these reasons, Applicants submit that claims 2, 5-7, 13-15, 17-20, and 22 are not anticipated by Nakamura.

Grouped Claims 8-9

Claims 8-9, each of which depend, either directly or ultimately, from claim 1, are not anticipated by Nakamura for the same reasons as stated above for the anticipation rejection of claim 1 in view of Nakamura. In addition, claims 8-9 each recite additional elements that further support patentability when combined with claim 1.

For example, claim 8 recites a compression device proximate the opening of the pouch. The term "compression device" is defined as a device that substantially conforms the pouch to the product both during and after dispensing. *See* e.g., Specification, page 3, lines 24-26; page 16, lines 1-2 and 12-13. No such device is disclosed in Nakamura.

Nakamura, on the other hand, does not teach a compression device proximate the opening 12 of container body 10. *See* Nakamura, Figure 13. The Examiner alleged that flap 14 may function as a compression device. However, there is no teaching identified that the flap 14 is a compression device as that term is defined in connection with the present invention, e.g., there is no teaching identified that the flap 14 can conform the pouch to the product. Rather, the flap is for repeatedly opening and sealing the dispensing opening 12 of the container body 10. *See* Nakamura, column 14, lines 38-39.

For at least these reasons, Applicants submit that claims 8-9 are not anticipated by Nakamura.

IV. Whether Claims 1, 2, 4-10, 12-16, 25-28, 32, 38-46, and 61-62 are anticipated under 35 U.S.C. § 102(b) by Parker et al. (U.S. Patent No. 5,003,970)

Claims 1, 2, 4-10, 12-16, 25-28, 32, 38-46, and 61-62 were rejected under 35 U.S.C. § 102(b) as being anticipated by Parker et al.

Grouped Claims 1-2, 4-7, 13-16, and 61

In the final Office Action dated 5 November 2001, the Examiner alleged that Parker et al. teaches all of the elements of claims 1-2, 4-7, 13-16, and 61. Specifically, the Examiner alleged that Figures 13-14 of Parker et al. teach a moisture sensitive product 14 that includes a plurality of sections, i.e., the layers seen in Figure 13, where each section includes two folds (at the edges) and a spanning segment (the middle portion of a layer) that extends along the pouch length.

In the Advisory Action dated 4 February 2002 at page 3, the Examiner alleged that the alleged "segment" that "spans the distance between the two folds has a component that is 'along the pouch length' as claimed."

Claims 1 and 61

With respect to claims 1 and 61, Applicants submit that Parker et al. fails to teach each and every element of the claims and, for that reason, is not an anticipatory document.

Claim 1 recites a continuous length product folded into a packaged configuration including a plurality of sections arranged along the pouch length, where each section includes at least two folds and a segment spanning therebetween, the segment also extending along the pouch length. Claim 61 further recites a moisture-curable orthopedic splinting/casting product.

Parker et al., on the other hand, is directed to a roll form medical bandaging product. In particular, Parker et al. describes a container 31 with an elongate dispensing sleeve 32 that has an openable end 33 through which the medical material 14 in the container 31 is dispensed. A coil

of the medical material 14 is positioned in an enlarged product storage package 34 that is integral and communicates with dispensing sleeve 32 (*see*, e.g., column 6, lines 22-28; Figures 11 and 14).

Applicants submit that the Examiner fails to identify a continuous length product folded into a packaged configuration including a plurality of sections arranged along the pouch length, where each section includes at least two folds and a segment spanning therebetween, the segment also extending along the pouch length (as discussed above, the phrase "extending along the pouch length" is defined in the specification and illustrated in the Figures as being oriented parallel to the pouch length or otherwise corresponding to the dispensing direction, *see* e.g., Specification at page 10, lines 30-32).

The Examiner relies on Figure 13 of Parker et al. to substantiate this rejection. In this view, a cross section, taken along line 13-13 of Figure 12, shows the medical material, which includes a "substrate 16 comprised of a suitable number . . . of overlaid fibers of a . . . fabric . . . contained within a tubular wrapping 18 [see Figure 5] which is formed of a soft, flexible . . . fiber . . . to provide a cushioning protective layer between the skin of the patient and substrate 16." Parker et al., column 5, lines 24-32. That is, the medical material includes the substrate 16 and the wrapping 18.

The Examiner, apparently in view of Figure 13 of Parker et al., alleged that the patent teaches "a plurality of sections (the layers seen in Fig 13), . . . [with] each section comprising two folds (at the edges) and a spanning segment (the middle portion of a layer) which extends along the pouch length." *See* final Office Action at page 3. Applicants submit, however, that such a configuration, even if disclosed by Parker et al., does not anticipate the claims.

For example, if the Examiner is relying on the two folds which are "at the edges" in Figure 13, then any alleged segment that "spans between" these two folds must necessarily extend between the edges, i.e., across the width of (transverse to) the material. Such a configuration is clearly not "along the pouch length" as claimed and described by Applicants. As a result, Parker et al. fails to anticipate claims 1 and 61 and the claims that depend therefrom.

It is further noted that the Examiner's rejection of claims 1 and 61 based on Figure 13 of Parker et al. relies not on the configuration of the medical material itself, but rather on the configuration of the substrate fibers that form only a portion of the medical material. That is, the Examiner is equating the weave configuration of the fiber substrate of the medical material 14 to the folded configuration of the actual moisture-sensitive product claimed by Applicants. The actual medical material or product of Parker et al. is the rolled product illustrated in Figure 14. Comparison of the fibers of Parker et al. to the product of the present invention is insufficient to establish anticipation.

Further, in the Advisory Action dated 4 February 2002 at page 3, the Examiner maintains that Parker et al. teaches that "the segment which spans the distance between the two folds has a component which is 'along the pouch length' as claimed." Applicants traverse this allegation. For example, claim 1 does not recite that a component of the segment also extends along the pouch length. Instead, claim 1 recites that the segment also extends along the pouch length.

Because anticipation requires that the identical invention be found in as complete detail as is recited in the claim (*see* M.P.E.P. § 2131), the Examiner has not met the burden for establishing anticipation based on Parker et al. For at least these reasons, it is submitted that claims 1 and 61 are not anticipated by Parker et al.

Claims 2, 4-7, and 13-16

Claims 2, 4-7, and 13-16, all of which depend, either directly or ultimately, from independent claim 1, are not anticipated by Parker et al. for the same reasons as presented above for claim 1. In addition, claims 2, 4-7, and 13-16 each recite additional elements that further support patentability when combined with claim 1.

For example, with regard to claims 15 and 16, Parker et al. does not teach a folded product configuration that includes at least two sections that each form an S-shape. That is, the material 14 (the substrate 16 and a single tubular sleeve 18) of Parker et al. does not include even a single section that forms an S-shape. *See,* e.g., Figures 4 and 5.

For at least the above reasons, Applicants submit that claims 2, 4-7, and 13-16 are not anticipated by Parker et al.

Grouped Claims 8-10, 12, 25-28, 32, 38-41, and 62

The Examiner, in the final Office Action dated 5 November 2001, alleged that Parker et al. teaches every element of claims 8-10, 12, 25-28, 32, 38-41, and 62. In particular, the Examiner alleged that clamp 36 taught by Parker et al. is equivalent to the compression device recited by the present invention because clamp 36 has two opposing, compressible members that are biased towards one another. The Examiner further alleged that the clamp 36 of Parker et al. shapes the end of the pouch to the shape of the product.

Claims 8-10 and 12

Claims 8-10 and 12, which depend from claim 1, are not anticipated by Parker et al. for the same reasons as presented above for claim 1. In addition, claims 8-10 and 12 each recite additional elements that further support patentability when combined with claim 1.

For example, claim 8 recites that the apparatus of the present invention further includes a compression device proximate the opening. The compression device is defined as a device that substantially conforms the pouch to the product both during and after dispensing. *See* e.g., Specification, page 3, lines 24-26. Words must be given their plain meaning unless applicant has provided a clear definition in the specification. *In re Zletz*, 13 U.S.P.Q.2d 1320, 1322 (Fed. Cir. 1989). The compression device is provided to reduce moisture intrusion during dispensing of the product. *See* Specification, page 7, lines 30-33. In contrast, Parker et al. does not teach a compression device that substantially conforms the pouch to the product both during and after dispensing.

Nonetheless, the Office Action alleges that clamp 36 of Parker et al. is a compression device within the meaning of claim 8. However, Applicants submit that the clamp 36 cannot conform the pouch to the product during dispensing because the clamp 36 must be removed in order for the user to grasp the product to be dispensed. See Parker et al., column 6, lines 56-58

("A desired length of medical material 14 is dispensed by removing clamp 36 or unzipping zippers 38 and grasping the exposed end of the medical material 14.").

Further, for example, claim 12 recites that the compression device is adapted to substantially conform the shape of the pouch to the shape of the product. As stated above, clamp 36 of Parker et al. cannot substantially conform the pouch to the product both during and after dispensing because the clamp 36 must be removed in order for the user to grasp the product to be dispensed.

Therefore, Parker et al. does not teach a compression device as claimed and, as such, claims 8-10 and 12 are not anticipated by Parker et al.

Claim 25

Claim 25 was also rejected under 35 U.S.C. § 102(b) as being anticipated by Parker et al.

As discussed above, Parker et al. does not teach a compression device as claimed and defined by the present invention, e.g., a device that substantially conforms the pouch to the product. For example, the alleged compression device of Parker et al., i.e. clamp 36, has to be removed prior to dispensing material 14 and therefore cannot reduce moisture intrusion during dispensing of material 14.

Moreover, contrary to the Examiner's allegations, there is no teaching that Figure 11 (or any other portion of Parker et al.) shows the clamp 36 conforming the shape of the pouch to the product (*see* final Office Action at page 7). In fact, the Specification (*see* e.g., column 6, lines 61-64, "When the proper length has been dispensed through opening 33, it is cut and the end is tucked back into the dispensing sleeve 32.") and the figures (*see* e.g., Figure 12) of Parker et al. indicate that the clamp 36 or zipper 38 function by tucking the material back into the sleeve and sealing the sleeve with the clamp or zipper.

As a result, Parker et al. does not anticipate claim 25.

Claims 26-28, 32, and 38-41

Claims 26-28, 32, and 38-41, each of which depend, either directly or ultimately, from independent claim 25, are not anticipated by Parker et al. for the same reasons as presented above for claim 25. In addition, claims 26-28, 32, and 38-41 each recite additional elements that further support patentability when combined with claim 25. As a result, it is requested that each dependent claim be examined based upon its own elements.

For example, the Examiner does not identify any teachings that anticipate the parallel closure device of claim 28. Moreover, claim 32 explicitly recites that the compression members conform the shape of the first end of the pouch to the shape of the product as the product is dispensed from the pouch through the opening. As mentioned above, the alleged compression device taught by Parker et al., i.e. clamp 36, must be removed prior to dispensing material 14; therefore, the clamp 36 cannot conform the shape of the first end of the pouch to the shape of the product as the product is dispensed from the pouch through the opening.

In the Advisory Action dated 4 February 2002 at page 4, the Examiner, without any support, alleges that the "compression members of Parker are capable of conforming the first end of the pouch to the shape of the product as the product is dispensed from the pouch." As repeatedly stated above, Parker et al. teaches that the claim 36 must be removed prior to dispensing material 14. *See,* e.g., *id.* at column 6, lines 56-58 ("A desired length of medical material 14 is dispensed by *removing* clamp 36 or unzipping zippers 38 and grasping the exposed end of the medical material 14."). As a result, the allegation is simply not supported by the reference.

For these and other reasons, Applicants submit that claims 26-28, 32, and 38-41 are not anticipated by Parker et al.

Claim 62

Claim 62 was also rejected under 35 U.S.C. § 102(b) as being anticipated by Parker et al.

Applicants submit that Parker et al. does not teach all of the elements of claim 62. For example, claim 62 recites a compression device that includes a first compressible member and a

second, opposing compressible member. The first and second compressible members are "adapted to substantially conform the shape of the first end of the pouch to the shape of the product."

As mentioned above, the clamp 36 taught by Parker et al. must be removed prior to dispensing material 14. In fact, Parker et al. makes clear that the material must be "tucked back in the pouch" before the clamp 36 can even be used (*see* column 6, lines 61-64). Such a clamp clearly fails to anticipate a compression device that "substantially conforms the shape of the first end of the pouch to the shape of the product."

For at least these reasons, Applicants submit that claim 62 is not anticipated by Parker et al.

Grouped Claims 42-46

The Examiner rejected claims 42-46 under 35 U.S.C. § 102(b) as being anticipated by Parker et al. Specifically, the Examiner alleged that the clamp 36 taught by Parker et al. includes a compression device including two opposing compression members (the two curved arms of the device), and a sealing device coupled to the compression device. The Examiner alleged that the sealing device (i.e., clamp 36) includes opposed sealing members (the flat pressing sections of the device). The Examiner further alleged that the semi-circular portion of clamp 36 is equivalent to a frame assembly that couples the compression and sealing devices together.

Claim 42

The Examiner rejected claim 42 under 35 U.S.C. § 102(b) as being anticipated by Parker et al.

Applicants submit that Parker et al. does not teach each and every element of claim 42. For example, Parker et al. does not teach both a compression device and a sealing device. In fact, as mentioned above, Parker et al. does not teach a compression device at all.

The Examiner alleges, however, that the two curved arms of clamp 36 (of Parker et al.) are equivalent to the compression device having two opposing compression members as claimed.

Applicants disagree. The two curved arms of clamp 36 (or any other part of the clamp for that matter) are not identified as being capable of doing anything but biasing the clamp , i.e., sealing device, to seal the sleeve after the product has been dispensed.

As Parker et al. fails to teach the identical invention in as complete detail as recited within claim 42, it fails to anticipate the claim.

Claims 43-46

Claims 43-46 were also rejected under 35 U.S.C. § 102(b) as being anticipated by Parker et al. Applicants traverse this rejection as these claims depend, either directly or ultimately, from independent claim 42. Thus, claims 43-46 are not anticipated by Parker et al. for the same reasons as presented above for claim 42. In addition, claims 43-46 each recite additional elements that further support patentability when combined with claim 42.

For example, claim 43 provides a frame assembly (*see* e.g., Figures 8 and 9) operatively coupling the compression device to the sealing device. Once again, because Parker et al. fails to even disclose a compression device as claimed, it necessarily cannot disclose a frame assembly associated therewith. Parker et al. therefore cannot anticipate claim 43.

The Examiner, however, alleges that the semi-circular portion of clamp 36 taught by Parker et al. is a "frame assembly" which couples the compression and sealing devices together. However, the Examiner has not identified any portion of the clamp 36 which functions as a compression device. Therefore, even considering all of the assumptions made by the Examiner, the clamp 36 of Parker et al. fails to teach a frame assembly that operatively couples a "compression device" to the sealing device, as is recited in claim 43.

For at least the above reasons, Applicants submit that claims 43-46 are not anticipated by Parker et al.

V. Whether claim 23 is unpatentable under 35 U.S.C. § 103(a) over Nakamura

The Examiner rejected claim 23 under 35 U.S.C. § 103(a) as being unpatentable over Nakamura. Specifically, the Examiner alleged that it would have been obvious to one of

ordinary skill in the art at the time the invention was made to move the suspension member 19 of Nakamura to either end of the pouch 10 for the purpose of better suiting the dispensing process to a given position or orientation.

Claim 23, which depends from independent claim 1, includes all of the elements recited in claim 1. As mentioned above in regard to the 35 U.S.C. § 102(b) rejection of claim 1, Nakamura does not teach all of the elements of claim 1. For example, Nakamura does not teach a moisture-sensitive product within the clear meaning given in the present invention. Further, Nakamura does not teach the plurality of sections and the configuration of the segments (e.g., along the pouch length) as recited in claim 1 (*see* discussion above regarding anticipation rejection of claim 1 in view of Nakamura). Further, claim 23 recites additional elements that further support patentability when combined with claim 1.

A proper *prima facie* obviousness rejection requires identification of some motivation or suggestion to modify the cited reference to reach the claimed invention. Further, the proposed modification must not render the prior art invention unsatisfactory for its intended purpose. If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). Here, the proposed modification of moving suspension member 19 of Nakamura to either end of the pouch 10 may render the pouch 10 unsatisfactory for its intended purpose. For example, moving the suspension member 19 to the opposite end of container body 10 may cause the container body 10 to leak out of either dispensing opening 12 or closure member 11. Subsequently, leaking may cause the wet tissues 3 to dry out.

For at least the above reasons, Applicants submit that claim 23 is patentable over Nakamura.

VI. Whether claim 29 is unpatentable under 35 U.S.C. § 103(a) over Parker et al. in view of Ausnit (U.S. Patent No. 4,703,518)

The Examiner rejected claim 29 under 35 U.S.C. § 103(a) as being unpatentable over Parker et al. in view of Ausnit. Specifically, the Examiner alleged that Parker et al. teaches all the limitations of claim 29 except the female member receiving the male member so that the pouch is trapped between. The Examiner alleged that Ausnit teaches a pouch locking system that has male and female members and that locks a pouch between the two members. The Examiner further alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the male/female sealing device into that of Parker et al. in order to produce a tighter seal.

Claim 29, which depends from claim 25, is not *prima facie* obvious because the cited references do not teach or suggest all of the elements of claim 29. As mentioned above in regard to the 35 U.S.C. § 102(b) rejection of claim 25, Parker et al. does not teach all of the elements of claim 25. For example, Parker et al. does not teach a compression device that substantially conforms the pouch to the product. The addition of Ausnit does nothing to address the above-mentioned deficiencies of Parker et al.

Further, no motivation or suggestion is identified by the Examiner to combine the plastic zipper taught by Ausnit with the container taught by Parker et al. For example, the zipper taught by Ausnit requires that the bag to which the zipper is attached have side seal seams 69 and holes 68 formed in the side seal seams. *See* Ausnit, column 4, lines 23-25. There is no teaching or suggestion identified that holes may be made in dispensing sleeve 32 of Parker et al. to accommodate the zipper mechanism/holes taught by Ausnit. In fact, including such holes in the dispensing sleeve 32 of Parker et al. may allow moisture to enter the sleeve and cause the medical material 14 to harden prematurely, thus rendering the invention unsatisfactory for its intended purpose.

For at least the above reasons, Applicants submit that claim 29 is not *prima facie* obvious in view of Parker et al. and Ausnit.

VII. Whether claims 11, 21, and 30-31 are unpatentable under 35 U.S.C. § 103(a) over Parker et al.

Claims 11, 21, and 30-31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Parker et al. Regarding claim 11, the Examiner alleged that it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate foam padding into the compression members of item 36 in order to prevent damaging the pouch 32. Regarding claims 21 and 30-31, the Examiner alleged that it would have been obvious to one of ordinary skill to attach a suspension member to an end of the pouch in order to hang the pouch for dispensing.

Claims 11 and 21

Parker et al. fails to render claims 11 and 21 obvious for several reasons. For example, Parker et al. fails to teach or suggest all of the elements of claim 1 from which these claims depend. As mentioned above in regard to the 35 U.S.C. § 102(b) rejection of claim 1, Parker et al. fails to teach, or even suggest, a moisture-sensitive product that is folded into a packaged configuration, wherein the packaged configuration includes a plurality of sections arranged within the interior and along the pouch length and further wherein each section of the packaged configuration includes at least two folds and a segment spanning therebetween, the segment of the packaged configuration also extending along the pouch length.

Instead, Parker et al. teaches a medical material 14 that is in a coiled packaged configuration. *See* Parker et al., column 4, lines 46-48; Figure 14. The coiled *packaged configuration* of Parker et al. does not have any folds, as is clearly seen in Figure 14. Further, there is no suggestion in Parker et al. to fold the product as claimed by Applicants.

In addition, claims 11 and 21 each recite additional elements that further support patentability when combined with claim 1. For example, claim 11 recites that each compression member includes a foam pad. The Examiner alleged that it would have been obvious to incorporate foam padding into the compression members of clamp 36 disclosed in Parker et al. in order to prevent damaging pouch 32. However, as mentioned above, Parker et al. does not teach

or even suggest a compression device that includes two opposing and compressible members biased towards one another, as is recited by claim 10 (from which claim 11 depends). Rather, Parker et al. teaches only a sealing device to seal the package shut. There is no teaching, suggestion, or motivation identified in Parker et al. that compressible members would be beneficial to the sealing device. In the absence of any identified support, one must conclude that the proposed modification is the result of impermissible hindsight.

The Office Action does not appear to address claim 21. Claim 21 provides that at least two sections each form a mushroom-shape. No teaching or suggestion is identified in Parker et al. of such a shape.

Claims 30 and 31

Applicants further submit that claims 30 and 31, which depend from independent claim 25, are not *prima facie* obvious because Parker et al. does not teach or suggest all of the elements of claims 30 and 31. For example, as mentioned above, Parker et al. fails to teach or suggest a compression device that substantially conforms the pouch to the product. Further, Parker et al. fails to teach or suggest a suspension member coupled to the pouch, as is specifically recited in claims 30 and 31. In the absence of any identified support, one must conclude that the proposed modification is the result of impermissible hindsight.

For the above reasons, Applicants submit that claims 11, 21, 30 and 31 are not *prima facie* obvious in view of Parker et al.

Summary

For the reasons provided herein, Applicants respectfully submit that pending claims 1-2, 4-23, 25-32, 38-46, and 61-62 are patentable in view of the cited references. Review and reversal of the rejections are respectfully requested.

CERTIFICATE UNDER 37 C.F.R. § 1.10:

The undersigned hereby certifies that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated below and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231
"Express Mail" number: EV 073 730 663 US
Date of Deposit: 9 May 2002
Signature: Lara Ladwig
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APPENDIX A - PENDING CLAIMS
Serial No.: 09/551,706
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For convenience, all pending claims are shown below.

1. An apparatus, comprising:

a pouch comprising a first end, a second end, and a pouch length extending therebetween, wherein the pouch further defines an interior; and

a moisture-sensitive product having a continuous length, the product being folded into a packaged configuration comprising a plurality of sections arranged within the interior and along the pouch length, each section comprising at least two folds and a segment spanning therebetween, the segment also extending along the pouch length.

2. The apparatus of claim 1, wherein the pouch further comprises an opening proximate the first end, the opening permitting access to the interior of the pouch.

4. The apparatus of claim 1, wherein the product comprises moisture-curable orthopedic splinting/casting product.

5. The apparatus of claim 1, wherein at least two of the sections are generally identical.

6. The apparatus of claim 1, wherein the pouch comprises at least one sheet of moisture-impervious material.

7. The apparatus of claim 1, wherein the continuous length product has a length at least two times the pouch length.

8. The apparatus of claim 2, further comprising a compression device proximate the opening.

9. The apparatus of claim 8, wherein the compression device is located on an exterior of the pouch.

10. The apparatus of claim 8, wherein the compression device comprises two opposing and compressible members biased towards one another.

11. The apparatus of claim 10, wherein each compression member comprises a foam pad.

12. The apparatus of claim 8, wherein the compression device is adapted to substantially conform the shape of the pouch to the shape of the product.

13. The apparatus of claim 2, further comprising a sealing device proximate the opening.

14. The apparatus of claim 1, wherein the pouch comprises a pouch width measured transversely to the pouch length, wherein the pouch width is substantially constant along the pouch length.

15. The apparatus of claim 1, wherein at least two sections each comprise only two folds and one segment therebetween.

16. The apparatus of claim 15, wherein the at least two sections each form an S-shape.

17. The apparatus of claim 1, wherein at least two sections each comprise three segments, each of the segments being bounded at both ends by folds.

18. The apparatus of claim 17, wherein at least two of the three segments are substantially equal in length.

19. The apparatus of claim 17, wherein each of the three segments are substantially equal in length.

20. The apparatus of claim 17, wherein each section comprises at least four folds.

21. The apparatus of claim 17, wherein the at least two sections each form a mushroom-shape.

22. The apparatus of claim 1, further comprising a suspension member.

23. The apparatus of claim 22, wherein the suspension member is located proximate the second end.

25. An apparatus for storing and dispensing a continuous length of product, the apparatus comprising:

a pouch comprising an interior for receiving and storing a continuous length of moisture-sensitive product, wherein the pouch further comprises a first end; and

a compression device adapted to couple to the pouch proximate the first end, the compression device comprising a first compression member and a second, opposing compression member, the compression members adapted to substantially conform the shape of the first end of the pouch to the shape of the product.

26. The apparatus of claim 25, further comprising an opening proximate the first end, the opening permitting access to the product within the interior of the pouch.

27. The apparatus of claim 26, further comprising a sealing device adapted to substantially seal the opening.

28. The apparatus of claim 27, wherein the sealing device forms a parallel closure device.

29. The apparatus of claim 28, wherein the parallel closure device comprises a male member and a female member, the female member adapted to receive the male member such that the pouch is trapped therebetween.

30. The apparatus of claim 25, further comprising a suspension member coupled to the pouch.

31. The apparatus of claim 30, wherein the suspension member is located proximate a second end of the pouch.

32. The apparatus of claim 26, wherein the compression members conform the shape of the first end of the pouch to the shape of the product as the product is dispensed from the pouch through the opening.

38. The apparatus of claim 25, wherein the moisture-sensitive product comprises a moisture-curable product.

39. The apparatus of claim 25, wherein the moisture-sensitive product comprises a moisture-curable splinting/casting product.

40. The apparatus of claim 25, wherein the first and second compression members are biased towards one another and further wherein at least one of the compression members is compressible.

41. The apparatus of claim 25, wherein the pouch is elongated, and further wherein the compression device is selectively movable along a length of the elongated pouch.

42. A closure apparatus for use with products stored within a flexible pouch, the apparatus comprising:

a compression device comprising two opposing compression members;

a sealing device operatively coupled to the compression device, the sealing device comprising opposing sealing members wherein the sealing members are selectively movable between an open position and a closed position.

43. The closure apparatus of claim 42, further comprising a frame assembly operatively coupling the compression device to the sealing device.

44. The closure apparatus of claim 42, further comprising a pouch containing a product, wherein the pouch has a first end with an opening therein, the closure apparatus securable to the pouch proximate the first end.

45. The closure apparatus of claim 44, wherein the compression members are adapted to substantially conform the shape of the pouch to the shape of the product.

46. The closure apparatus of claim 44, wherein the sealing device is adapted to selectively seal the opening of the pouch.

61. An apparatus, comprising:

a pouch comprising a first end, a second end, and a pouch length extending therebetween, wherein the pouch further defines an interior; and

a moisture-curable orthopedic splinting/casting product having a continuous length, the product being folded into a packaged configuration comprising a plurality of sections arranged within the interior and along the pouch length, each section comprising at least two folds and a segment spanning therebetween, the segment also extending along the pouch length.

62. An apparatus for storing and dispensing a continuous length of moisture-sensitive product, the apparatus comprising:

a pouch comprising an interior for receiving and storing the continuous length of moisture-sensitive product, wherein the pouch further comprises a first end; and

a compression device adapted to couple to the pouch proximate the first end, the compression device comprising a first compressible member and a second, opposing compressible member, the first and second compressible members adapted to substantially conform the shape of the first end of the pouch to the shape of the product.